REMARKS

Upon entry of the instant amendment claims 34 to 55 will be pending. The Office Action dated October 31, 2006 has been carefully reviewed and the following reply is made in response thereto. In view of the amendments and the following remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Summary of Office Action

1. Rejections under 35 U.S.C. § 112, second paragraph, for claims 52 and 53 have been withdrawn.

2. Rejections under 35 U.S.C. § 112, for claim 48 has been withdrawn.

3. Claims 34-42 and 45-55 are rejected under 35 U.S.C. § 103(a) as unpatentable over Latham *et al.* and Saito *et al.*

4. Claims 34 and 43-45 are rejected under 35 U.S.C. § 103(a) as unpatentable over Latham *et al.*, Saito *et al.* and Gupta *et al.*

Summary of Meeting with Examiners

Applicants would like to thank Examiners Hill and Campell for their courteous and helpful discussions held with Applicants' representatives on March 22, 2007. During the meeting Applicants' representatives and Examiners Hill and Campell discussed the 35 U.S.C. § 103(a) rejections as they relate to the art and the use of inherency. Applicants submit that inherency cannot be used in 35 U.S.C. § 103(a) rejections. Examiner Campell provisionally agreed with Applicants' agents regarding using inherency in 35 U.S.C. § 103(a) rejections and stated that he will look at the case law to confirm. Examiners then stated that they would reconsider the 35 U.S.C. § 103(a) rejections. In addition, Examiners stated that the 35 U.S.C. § 103(a) rejections could be overcome by a showing of unexpected results.

Rejections under 35 U.S.C. § 103

The Examiner has rejected claims 34-42 and 45-55 under 35 U.S.C. § 103(a) as obvious under Latham *et al.* (J. of Virology 75, 6154-6165) in view of Saito *et al.* (Vaccine 20, 125-133).

Specifically the Examiner asserts that Latham *et al.* discloses VLPs comprising HA, NA, M1 and M2 but does not teach avian influenza. Saito *et al.*, according to the Examiner, discloses H9N2, thus alleging that one of ordinary skill in the art would have been motivated to make H9N2 VLPs. In addition, the Examiner also asserts that expression of HA and NA is well known in the art to have enzymatic activity (*i.e.* this is an inherent feature of the proteins).

Applicants traverse this rejection and assert that the Examiner has not met his burden of establishing a *prima facie* case of obviousness. "To establish *prima facie* obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art" (MPEP 2143.03). In the pending rejection, for instance, Applicants assert that none of the cited references disclose an influenza VLP, wherein the HA and/or the NA exhibit activity, let alone an avian VLP wherein the HA and/or NA exhibit activity. Although the Examiner asserts that expression of HA and NA are well known in the art to have enzymatic activity (Office Action bridging pages 3-4), the Examiner has failed to provide a reference to support such an assertion.

In addition, Applicants respectfully refer the Examiner to § 2141.02 of the MPEP which states that "[o]bviousness cannot be predicated on what is not known at the time an invention is made, even if the inherency of a certain feature is later established." The Federal Circuit has consistently upheld this doctrine. Further, it is well settled that consideration of an inherent quality is generally relevant only to anticipation, not obviousness. *Jones v. Hardy*, 220 USPQ 1021, 1025 (Fed. Cir. 1984), emphasis added.

The Examiner further asserts that the VLPs of the Latham *et al.* VLPs are made by insect cells and would be expected to have the same properties (see Office Action page 3). In other words, the Examiner urges Applicants to accept the proposition that if a prior art reference discloses the same structure as claimed, the resulting property should be assumed. Applicants decline to adopt this approach because this proposition is not in accordance with the case law on inherency and is inconsistent with the instant claims. As to the Examiner's assertion that the VLPs in Latham *et al.* look like the VLPs in the claims, Applicants direct the Examiner's attention to the claim structure that require avian HA and/or NA. Also, according to the case law on inherency, if the HA and NA activity limitation is inherently disclosed by the art, it must be necessarily present and a person of ordinary skill in the art would recognize its presence. *In re Robertson*, 169 F.3d 743, 745, (Fed. Cir. 1999); *Continental Can*, 948 F.2d at 1268 (Inherency

"may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.") *Id.* at 1269. In insisting that there is inherent disclosure of the HA and NA activity in the art, the Examiner bears an evidentiary burden to establish that the limitation was necessarily present. In this case, the Examiner provides no evidence of such activity.

Assuming, *arguendo*, that the Examiner can cite to a reference showing that HA and NA do have enzymatic activity when expressed, it cannot be presumed that the HA and NA in Latham *et al.* VLPs are active. To express a protein that exhibits activity, the protein must be folded in the correct conformation. Expression and folding is a complex process that may not yield proteins with activity, especially in an *in vivo* system. The references cited above, especially the Latham *et al.* reference, do not show nor suggest that the disclosed influenza HA or NA components in the VLP exhibit activity. Applicants also remind examiner that inherency has no place in a rejection under 35 U.S.C. § 103 (see § 2141.02 "[o]bviousness cannot be predicated on what is not known at the time an invention is made, even if the inherency of a certain feature is later established."). Thus, Applicants assert that the Examiner has not met his burden of establishing a *prima facie* case of obviousness. Thus, Applicants request that this rejection under 35 U.S.C. § 103 be reconsidered and withdrawn.

The Examiner has rejected claims 34, and 43-44 under 35 U.S.C. § 103(a) as being unpatentable over Latham *et al.* and Saito *et al.* in view of Gupta *et al.*(Vaccine 3, 219-225). Specifically the Examiner asserts that Latham *et al.* and Saito *et al.* disclose avian VLPs and Gupta *et al.* discloses Novasomes, thus rendering the claims obvious.

Applicants traverse this rejection and assert that the Examiner has not met his burden of establishing a *prima facie* case of obviousness. "To establish prima facie case of obviousness of a claimed invention, all claim limitation must be taught or suggested by the prior art" (MPEP 2143.03). As stated above, Latham *et al.* and Saito *et al.* do not teach an avian influenza VLPs let alone an avian influenza VLP that has HA or NA activity (see above argument). Gupta *et al.* does not disclose influenza vaccines in combination with adjuvants. Thus, the combined references do not teach or suggest all the claim elements. Therefore, the Examiner has not established a *prima facie* case of obviousness. In view of the above argument, Applicants request that this rejection be reconsidered and withdrawn.

Conclusion

Applicant respectfully requests reconsideration of the subject application in view of the amendments to the claims and the above remarks. It is respectfully submitted that this application is now in condition for allowance. Should the Examiner feel that there are any issues outstanding after consideration of this amendment; the Examiner is requested to contact the Applicant's undersigned representative.

If there are any fees due in connection with the filing of this amendment, please charge the fees to our Deposit Account No. **50-1283**. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

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Respectfully submitted,
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